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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/077,606	07/30/98	JIANG	P 040388/0113

FOLEY & LARDNER  
3000 K STREET N W  
PO BOX 25696 SUITE 500  
WASHINGTON DC 20007-8696

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EXAMINER

TUNG, M

ART UNIT	PAPER NUMBER
1644	16

DATE MAILED: 08/29/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

# Office Action Summary

Application No.  
09/077,606

Applicant(s)  
Jlang, et al.

Examiner  
Mary B. Tung

Group Art Unit  
1644



☒ Responsive to communication(s) filed on Apr 27, 2000

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-11, 23, 24, 33-38, and 42-89 is/are pending in the application

Of the above, claim(s) 1-11, 23, 24, and 33-38 is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 42-72, 74, 76, 80-82, 84, 86, and 88 is/are rejected.

☒ Claim(s) 73, 75, 77-79, 83, 85, 87, and 89 is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 14

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

**DETAILED ACTION**

Claims 1-41 were originally presented.

Claims 39-41 were cancelled in the paper filed June 2 1998, Paper No. 5.

Claims 12-22 and 25-32 were cancelled in the paper filed 4/27/00, Paper No. 15.

Claims 42-89 were added in Paper No. 15.

Claims 1-11, 23, 24 and 33-38 stand directed to a non-elected invention.

***Information Disclosure Statement***

1. The information disclosure statement filed 4/27/00, Paper No. 14 was filed after the mailing of the First Action on the Merits, but before a Final Rejection. In the absence of a certification under 37 C.F.R. 1.97(c)(1), a fee of \$240 will be charged to the Applicants' listed deposit account of 19-0741, as authorized in Paper No. 14.

2. The corrections and resubmissions of the Kaba reference and reference A5 (Jiang, et al, 1983) is noted. Reference A5 has been lined through in Paper No. 2, as being duplicative. The Examiner thanks the Applicants for their attention in these corrections.

*In light of the cancellation of all claims previously examined, all rejections in the action mailed 10/27/99 are hereby withdrawn.*

*The following new grounds for objection and rejection are necessitated by amendment:*

***Claim Rejections - 35 U.S.C. § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

4. Claims 42, 47, 52-60, 65, 70, 71, 80 and 81 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

5. SEQ ID NO: 1, recited in the claims, is a nucleic acid sequence, not an amino acid sequence. For the purposes of examination, the amino acid translation, in all 6 reading frames, was searched for SEQ ID NO: 1. If the amino acid sequence translated from SEQ ID NO: 1 is not separately listed in the sequence listing, the Applicants are

required to submit a new sequence listing and a computer readable diskette including the sequence. However, upon visual inspection, it appears that the translated amino acid sequence from SEQ ID NO: 1 is the amino acid sequence of SEQ ID NO: 3. The Applicants are invited to carefully review the sequence listing and amend the claims and/or the sequence listing accordingly.

6. Claims 52 and 54 contain the trademark/trade names SEPHACRYL S-200 and CM-TRISACRYL-M. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe the chromatography solid phase materials and, accordingly, the identification/description is indefinite. Applicants are required to define the composition of the materials in more detail to overcome the rejection. The definitions as amended define the two trademarked compositions as being the same. They clearly are not the same. The size of the linkers, the polarity or charge, size of the agarose, and so forth probably differ one from the other. These characteristics need to be included the first time the products are recited in the claims.
7. Claims 52-54 and 57-59 are indefinite in the use of the abbreviations HPLC, SDS-PAGE, and DEAE. The terms must be defined the first time they are recited in the claims.

***Claim Rejections - 35 U.S.C. § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 42-53, 60-69, 70, 72, 74, 76, 80, 82, 84, 86 and 88 are rejected under 35 U.S.C. 102(b) as being anticipated by Zeng, et al. (*Biol. Chem. Hoppe-Seyler*, 375:393-399).
10. Zeng teaches a lectin, sarcolectin, identified as a human albumin, which contain at least a part of an amino acid sequence of the recited sequence (see the abstract and Fig. 3) as recited in claim 12, that retain MIF binding lectinic activity (see the abstract) as recited

in claim 16, in a process wherein the compounds were extracted from tissue (human placenta, see page 398, col. 1, paragraph 3) using Sephacryl S-200 and DEAE cellulose, using N-acetylneuraminic acid as a ligand (see page 398, col. 1, paragraph 3), as recited in claim 52, wherein the stage of affinity chromatography comprises the use of an agarose gel column on which is fixed a sugar (Sephacryl S-200 comprises agarose and the sugar dextran) and the use of at least 2 buffers (PBS and glycine/HCL, see page 398, col. 2, paragraph 1), and lowering the pH to 5 (acidic pH), as recited in claim 30 (see page 397, col. 1, paragraph 1). The sarcolectin taught by Zeng is the same as the disclosed sarcolectin despite the absence of the teaching of CM-Trisacryl-M, as recited in claims 52 and 53 since a product is a product regardless of its method of manufacture, unless the method of manufacture materially alters the product. Additionally, the sarcolectin in PBS would constitute an agent suitable for therapeutic use, as recited in claims 70, 72, 74, 76, 78, 80, 82, 84, 86 and 88. Therefore, the reference teaching anticipates the claimed invention.

11. Applicant's arguments filed in Paper No. 15, as applied to now cancelled claims 12, 16, 21, 22, 25-27 and 30-32 and now applied to newly-added claims 42-53 and 60-69 have been fully considered but they are not persuasive.
12. The Applicants argue that the product of Zeng, et al. is not as purified as the product of the Applicants, and thus is not the same product. However, the Applicants' arguments and the recited peptide of claims 52 and 53 is claimed as a product by process. Where the claimed and prior art products are identical or substantially identical in structure or are produced by identical or substantially identical processes, a *prima facie* case of anticipation has been established. When the PTO shows a sound basis for believing that the products of the Applicants and the prior art are the same, the Applicants has the burden of showing that they are not. *see MPEP 211.01*. Therefore, absent evidence to the contrary, the product of Zeng, et al and the claimed product are the same, absent evidence to the contrary. Also, the mere act of sequencing a known protein, does not render the known polypeptide patentable, since the sequence is an inherent property of the polypeptide. Claims 60-69 recite intended use limitations, which lend no patentable weight to the claims. A product is a product, regardless of its intended use. Additionally, the sarcolectin in PBS would constitute an agent suitable for therapeutic use, as recited in claims . Therefore, the reference teaching anticipates the claimed product.
13. Claims 45, 47-50, 63 and 65-68 are rejected under 35 U.S.C. 102(b) as being anticipated by Glass and Fuchs (*J. Cell Biol.* 101:2366-2373, 1985).
14. Glass and Fuchs teach a 469 amino acid polypeptide encoded by SEQ ID NO: 1, with 98.5% identity over its entire length with SEQ ID NO: 3 of the instant application, 97.0% identity with residues no. 2-135 of SEQ ID NO: 4 of the instant application,

and 100% identity with SEQ ID NO: 5 of the instant application (see Figure 6, GenBank Accession No. P08729 and B24177). The keratin taught by Glass and Fuchs is the same as the disclosed sarcolectin despite the absence of the teaching of the process for separation, as recited in claims 52 and 53 since a product is a product regardless of its method of manufacture, unless the method of manufacture materially alters the product. Therefore, the reference teaching anticipates the claimed invention.

The Applicant's arguments, applied to now cancelled claims 12-22 and now applied to newly-added claims 45, 47-50, 63 and 65-68 are that keratins have properties totally different from the properties of sarcolectins and cannot be present in serum as can sarcolectins. However, the sequences recited in SEQ ID NO: 3, 4 and 5, would inherently have the lectinic characteristics disclosed in the specification on page 1, as the amino acid sequences are identical over the entirety of SEQ ID NO: 5, over the entire sequence of SEQ ID NO: 4, absent amino acid residue no. 1, and only 2 mismatches over the entire length of SEQ ID NO: 3. The fact that the protein of Glass and Fuchs is present in multimeric form, does not preclude the sequences from having the claimed "lectinic properties" of the Applicants protein, since especially with SEQ ID NO: 5, the sequence is the same. In regard to the sequence of SEQ ID NOS: 3 and 4 and the translated protein of SEQ ID NO: 1, the Applicants are invited to provide evidence that the proteins of Glass and Fuchs would not have the recited properties. The recitation of claims 47-51, wherein the amino acid of SEQ ID NOS: 3-6 and the translated protein of SEQ ID NO: 1, comprises the peptide or protein, would encompass the teachings of Glass and Fuchs, since the taught protein would be comprised by the claimed polypeptide. Additionally, since an epitope comprises more than 5 amino acids, an antibody specific to the claimed polypeptides would recognize the taught polypeptides.

15. Claims 45, 47-50, 63 and 65-68 are rejected under 35 U.S.C. 102(b) as being anticipated by Glass and Fuchs (*J. Cell Biol.* 107:1337-1350, 1988).
16. Glass and Fuchs teach a 469 amino acid polypeptide encoded by SEQ ID NO: 1, with 97.6% identity over its entire length with SEQ ID NO: 3 of the instant application, 94.0% identity with residues no. 2-135 of SEQ ID NO: 4 of the instant application, and 100 % identity with SEQ ID NO: 5 of the instant application (see Figure 6, GenBank Accession No. B24177). The keratin taught by Glass and Fuchs is the same as the disclosed sarcolectin despite the absence of the teaching of the process for separation, as recited in claims 52 and 53 since a product is a product regardless of its method of manufacture, unless the method of manufacture materially alters the product. Therefore, the reference teaching anticipates the claimed invention.

The Applicant's arguments, applied to now cancelled claims 12-22 and now applied to newly-added claims 45, 47-50, 63 and 65-68 are that keratins have properties totally

different from the properties of sarcolectins and cannot be present in serum as can sarcolectins. However, the sequences recited in SEQ ID NO: 3, 4 and 5, would inherently have the lectinic characteristics disclosed in the specification on page 1, as the amino acid sequences are identical over the entirety of SEQ ID NO: 5, over the entire sequence of SEQ ID NO: 4, absent amino acid residue no. 1, and only 2 mismatches over the entire length of SEQ ID NO: 3. The fact that the protein of Glass and Fuchs is present in multimeric form, does not preclude the sequences from having the claimed "lectinic properties" of the Applicants protein, since especially with SEQ ID NO: 5, the sequence is the same. In regard to the sequence of SEQ ID NOS: 3 and 4 and the translated protein of SEQ ID NO: 1, the Applicants are invited to provide evidence that the proteins of Glass and Fuchs would not have the recited properties. The recitation of claims 47-51, wherein the amino acid of SEQ ID NOS: 3-6 and the translated protein of SEQ ID NO: 1, comprises the peptide or protein, would encompass the teachings of Glass and Fuchs, since the taught protein would be comprised by the claimed polypeptide. Additionally, since an epitope comprises more than 5 amino acids, an antibody specific to the claimed polypeptides would recognize the taught polypeptides.

*Allowable Subject Matter*

17. Claims 73, 75, 77-79, 83, 85, 87 and 89 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

*Conclusion*

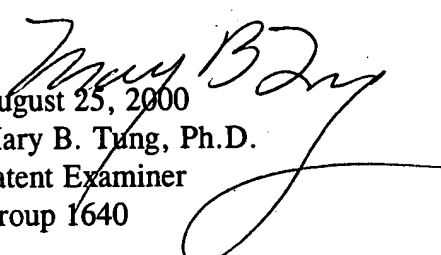
18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


19. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

20. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published

in the Official Gazette, 1096 OG 30 (November 15, 1989). THE CM1 FAX CENTER TELEPHONE NUMBER IS (703) 305-3014 or (703) 308-4242.

21. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Mary Tung whose telephone number is (703)308-9344. The Examiner can normally be reached Tuesday through Friday from 8:30 am to 6:00 pm, and on alternating Mondays. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1640 receptionist whose telephone number is (703) 308-0196.

  
August 25, 2000  
Mary B. Tung, Ph.D.  
Patent Examiner  
Group 1640

  
DAVID SAUNDERS  
PRIMARY EXAMINER  
ART UNIT 182/1644